



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,304	04/16/2001	Franz Josef Meyer-Almes	P66378US0	4840

136 7590 12/30/2003

JACOBSON HOLMAN PLLC
400 SEVENTH STREET N.W.
SUITE 600
WASHINGTON, DC 20004

EXAMINER

YU, MISOOK

ART UNIT	PAPER NUMBER
----------	--------------

1642

DATE MAILED: 12/30/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,304

Applicant(s)

MEYER-ALMES, FRANZ JOSEF

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment filed on 2-19-2003 is entered. Claims 12-26 are pending and examined on merits.

Claim Rejections - 35 USC § 112

Rejection of the claims (now all cancelled) under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is **applied to the new claims 27-41**. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are still interpreted as drawn to method of detecting apoptosis by measuring caspase activity by measuring fluorogenic change of **a genus of caspase substrate** containing DEVD.

Applicant argues as the art of record, Benzamin et al, and Martin et al of record shows fluorogenic substate comprising DEVD motif is well known in the art. However, this argument is not persuasive because both Benzamin et al, and Martin et al teach only one such substrate i.e. aminocoumarin-DEVD. However, the claims are drawn to any structure containing DEVD and aminocoumarin structure is also important for being fluorogenic. Note the previously provided Clontech catalog for fluorogenic activity of aminocoumarin-DEVD vs. cleaved aminocoumarin. The specification does not teach what other structures could be attached to DEVD to be a fluorogenic substrate to be used in the claimed screening method.

Rejection of the claims (now all cancelled) under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is **applied to the new claims 27-**

Art Unit: 1642

41. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant appears to argue that the detection method is well known in the art. However, this rejection is applied to the new claims because the specification does not teach how to make and how to use any other substrate comprising DEVD. However, this argument is treated not commensurate in scope of claims because aminocouarin-DEVD based assay is the only art-available method but the claims are drawn to method of using any substrate comprising DEVD. What other structures as a substrate could be used for the screening method? What is emission wavelength before the cleavage vs. after cleavage if any other substrate other than aminocouarin-DEVD exists?

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection. Claim 38 recites "the fluorogenic substrate is part of a lysis buffer to the sample for disruption of the cells." Example 1-3 at page 12-14 says lysis buffer was added and aminocoumarin-DEVD was added just after frozen lysate is thawed and just before lysis buffer is added. The Office is unable to find the support for the limitation in the instant claim. Applicant is requested to point out the support in the specification as originally filed. For art searching purpose,

the claim is interpreted as drawn to adding lysis buffer first, followed by adding the substrate just before measuring the emission of substrate and product.

Claim Rejections - 35 USC § 102

Rejection of the claims under 35 U.S.C. 102(b) as being anticipated by Martins et al (Dec. 1, 1997, Blood 90, pages 4285-4296) is now applied to the new claims 27-41.

Claims are interpreted as drawn to screening method using aminocouarin-DEVD based assay.

Applicant argues that the instant invention is measuring accumulated caspase activity and the art of record does not measure accumulated activity and the art of record separates off cells. This argument has been fully considered not persuasive because instant claims as constructed read on the art.

Martins et al teach, not only the separating off cells methods as applicant pointed out, the art also teach (note the last two sentences of the same paragraph applicant asked the Office to look at) method of measuring accumulated caspase activity without separating off cells. Note "Alternatively, etoposide was added to a final concentration of 68...continuously up to 48 hours (see the abstract)" without sedimentation. Also note Fig. 5C-E at page 4291, and page 4288, right column, the last paragraph where it teaches "cytosol from etoposide-treated cells was directly assayed using fluorogenic substrates". There is no difference between instantly claimed method in light of the preferred Example I of the accumulated caspase activity assay at page 12 of the instant specification and the art of record and the method described in the art of record. The

Art Unit: 1642

art teaches teach method of continuously incubating the substance without separating off the cells for caspase activity to detect delayed caspase activity, thus anticipating instant claims.

Any other rejection or objection not repeated in this Office action is withdrawn.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-

Application/Control Number: 09/762,304

Page 6

Art Unit: 1642

305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu

December 15, 2003

ANTHONY C. CAPOTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

9
ANTHONY C. CAPOTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600